

### **Remarks**

Claims 14-29, 35, 36, and 39-47 are pending upon entry of the foregoing amendment.

### **Examiner Interview**

Applicants thank the Examiner for the helpful telephonic interview on December 5, 2006, wherein it was agreed that the foregoing amendment would place the claims in condition for allowance. The Examiner agreed that the “array of discrete microtubes” of the instant claims is distinct, for example, from the device disclosed in U.S. Patent 5,797,898 to Santini Jr. et al.

### **Obviousness-Type Double Patenting Rejection**

Claims 14-18, 20-29, 35, 36, and 39-41 were rejected under the doctrine of obviousness-type double patenting in view of claim 1 of U.S. Patent No. 7,052,488 to Uhland (hereinafter “Uhland”), claim 1 of U.S. Patent No. 7,041,130 to Santini Jr. et al. (hereinafter “Santini ‘130’”), or claims 1, 22, and 31 of U.S. Patent No. 6,849,463 to Santini Jr. et al. (hereinafter “Santini ‘463’”). The rejections are respectfully traversed.

For the same reasons discussed in the Examiner Interview, it is respectfully submitted that this rejection is based on a misreading of the applied references. The instant claims are plainly not “a broader recitation of a previously claimed invention”, as detailed below.

#### **Uhland**

The device of claim 1 of Uhland requires *a substrate* in which are located at least two reservoirs. This substrate having multiple reservoirs is not remotely suggestive of an array of *discrete, metal microtubes* each having a single reservoir.

Furthermore, the device of claim 1 of Uhland includes a mechanical rupturing mechanism which comprises “a structure which moves, at the time selected for rupture of a reservoir cap, from a non-contacting position **outside** of the reservoir into contact with and

ruptures the reservoir cap to **permit release** of the therapeutic agent”. In contrast, the presently claimed device requires means for *positively displacing* chemical molecules. Uhland’s claim 1 suggests at most a passive release mechanism; the claim utterly fails to provide any motivation for including a means for *positively displacing* a therapeutic agent from the reservoir.

In sum, the structures which house the reservoirs and the means for releasing the molecules from those reservoirs are entirely non-obvious from one another. Claim 1 of Uhland does not remotely suggest the features defined by Applicants’ claim 14.

Santini ‘130

Claim 1 of Santini ‘130 specifies a device comprising a stent having reservoirs, discrete reservoir caps, and a release system contained in each reservoir. Claim 1 of Santini ‘130 fails to in any way suggest an array of discrete microtubes. Furthermore, Claim 1 of Santini ‘130 clearly does not require or remotely suggest a means for rupturing a rupturable covering and/or positively displacing a release formulation from a reservoir, as required by claim 14.

Santini ‘463

Claims 1, 22, and 31 of Santini ‘463 are directed to devices that have reacting components immobilized in reservoirs and barrier layers covering each reservoir. Claims 1, 22, and 31 of Santini ‘463 do not remotely teach or suggest a device composed of an array of discrete microtubes.

Furthermore, Claim 1 of Santini ‘463 requires a microprocessor controlled actuation means for disintegrating or permeabilizing the barrier layer *to expose* the reacting component. Similarly, Claims 22 and 31 of Santini ‘463 require control circuitry and a power source for selectively disintegrating the barrier layer *to expose* the reacting component. These processes for

exposing an immobilized reacting components neither disclose nor remotely suggest the positive displacement of a release formulation as required by the instant claims.

For any one or all of these reasons, the rejections should be withdrawn.

### **Rejections under 35 U.S.C. § 102**

Claims 14, 15, 22-27, 29, 35, and 36 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,797,898 to Santini Jr. et al. (hereinafter "Santini '898). The rejection is respectfully traversed.

#### **Applicants Claimed Devices**

Applicants have developed devices that include an array of *discrete microtubes* for the controlled release of chemical molecules. The microtubes are straight-walled structures, constructed of a metal or an alloy, which advantageously can be made with fewer (or no) MEMs processing steps as compared to other micro-reservoir devices. See page 15, lines 3-8. In addition, Applicants' claimed devices may include means for rupturing a rupturable covering and for positively displacing a release formulation from each microtube.

#### **Santini '898**

Santini '898 discloses a microchip device having a substrate in which a plurality of reservoirs is defined. The reservoirs contain a release system comprising chemical molecules for release. Release may be by diffusion through reservoir caps or following disintegration of reservoir caps. Santini '898 discloses that the substrate may be made of ceramics and semiconductors, such as silicon, into which the reservoirs can be etched. (Col. 2, Lines 10-12). Santini '898 does not disclose or suggest an array of **discrete microtubes**. Nor does the reference teach or suggest microtubes constructed of a *metal* or an *alloy*.

Moreover, nothing in Santini '898 discloses or suggests a means for *positively displacing* a release formulation through a reservoir opening. In sum, Santini '898 simply does not teach or suggest Applicants' devices that include an array of discrete metal or alloy microtubes as claimed.

**Rejections under 35 U.S.C. § 103**

Claims 16-20 and 42-47 were rejected under 35 U.S.C. § 103(a) as obvious over Santini '898 in view of U.S. Patent No. 6,200,293 to Kriesel et al. (hereinafter "Kriesel"). Claims 40 and 41 were rejected under 35 U.S.C. § 103(a) as obvious over Santini '898 in view of Kriesel, in further view of U.S. Patent No. 4,111,202 to Theeuwes (hereinafter "Theeuwes"). Claim 39 is rejected under 35 U.S.C. § 103(a) as obvious over Santini '898. Claim 21 was rejected under 35 U.S.C. § 103(a) as obvious over Santini '898 in view of U.S. Patent No. 5,911,737 to Lee et al. (hereinafter "Lee"). The rejections are respectfully traversed.

**Santini '898 In Combination With the Cited References**

As explained above, Santini '898 fails to disclose devices that include disclose or suggest an array of discrete microtubes constructed of a metal or an alloy, or means for positively displacing a release formulation through a reservoir opening. Nothing in Kriesel, Theeuwes, or Lee, alone or in combination, can be construed to supplement this deficiency.

Kriesel discloses an apparatus for infusing medical fluids comprising a reservoir, an infusion means, and a heat expandable mass which causes fluid in the reservoir to flow into the infusion means. The infusion means comprises a cannula covered with a twist-off protective sheath. Nothing in Kriesel, alone or in combination with Santini '898, remotely teaches a device having an array of discrete microtubes.

In addition, nothing in Kriesel, alone or in combination with Santini '898, remotely teaches a device having a means for *rupturing a rupturable covering* and positively displacing a release formulation through a reservoir opening. In contrast, Kriesel merely discloses a mechanism for infusing fluid through a cannula to a patient following manual removal of a protective sheath. Manual *removal* clearly is neither identical nor equivalent to *rupturing a rupturable covering*.

Theeuwes discloses an osmotic system for delivery of a drug from a body having a passageway through which the drug flows out. Nothing in Theeuwes, alone or in combination with Santini '898 and Kriesel, remotely suggests a device having an array of discrete microtubes.

Lee discloses microfabricated therapeutic actuators comprising shaped memory polymer microtubing for retaining and the releasing an embolic platinum coil, for example. Nothing in Lee, alone or in combination with Santini '898, remotely teaches a device having an array of discrete microtubes and means for rupturing a rupturable covering and for positively displacing a release formulation through a reservoir opening.

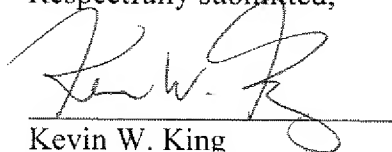
### **Conclusions**

For the foregoing reasons, it is submitted that the claims as amended are novel and non-obvious over the cited prior art. Prompt allowance of each of pending claims 14-29, 35, 36, and 39-47 is therefore respectfully solicited.

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AMENDMENT AND  
RESPONSE TO OFFICE ACTION

The undersigned kindly invites the Examiner to contact him by telephone (404.853.8068) if any outstanding issues can be resolved by conference or examiner's amendment.

Respectfully submitted,



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